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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,066	04/28/2005	Keiji Iwamoto	63286(46342)	5897
21874 7590 02/26/2007 EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			EXAMINER DANG, IAN D	
			ART UNIT	PAPER NUMBER
			1647	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
31 DAYS		02/26/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/533,066

Applicant(s)

IWAMOTO ET AL.

Examiner

Ian Dang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-41 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                      | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

## DETAILED ACTION

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 3-4, 8-11, drawn to a glucose uptake inhibitor in the small intestine comprising a compound or a salt thereof that inhibits the activity of a Na<sup>+</sup>/glucose transporter (SGLT) homolog.

Group II, claim(s) 2, drawn to a glucose uptake inhibitor in the small intestine comprising a compound or a salt thereof that inhibits the expression of a gene for Na<sup>+</sup>/glucose transporter (SGLT) homolog.

Group III, claim(s) 5-7, drawn to a glucose uptake inhibitor in the small intestine comprising a compound or a salt thereof that promotes the activity of a Na<sup>+</sup>/glucose transporter (SGLT) homolog.

Group IV, claim(s) 6, drawn to a glucose uptake inhibitor in the small intestine comprising a compound or a salt thereof that promotes the expression of a gene for Na<sup>+</sup>/glucose transporter (SGLT) homolog.

Group V, claim(s) 12-15, 21, and 27 drawn to a glucose uptake inhibitor in the small intestine comprising an antisense polynucleotide comprising the entire or part of a base sequence complementary or substantially complementary to a base sequence of a polynucleotide encoding a Na<sup>+</sup>/glucose transporter (SGLT) homolog.

Group VI, claim(s) 16-20, drawn to a glucose uptake inhibitor in the small intestine comprising an antibody to a Na<sup>+</sup>/glucose transporter (SGLT) homolog.

Group V, claim(s) 22-23, drawn to a method of screening a compound or its salt that regulates the glucose uptake activity of a Na<sup>+</sup>/glucose transporter (SGLT) homolog in the small intestine.

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Group VI, claim(s) 24, drawn to a kit for screening a compound or its salt that regulates the glucose uptake activity of a Na<sup>+</sup>/glucose transporter (SGLT) homolog in the small intestine comprising the SGLT homolog.

Group VII, claim(s) 25-26, drawn to a method of screening a compound or its salt that regulates the glucose uptake activity of a Na<sup>+</sup>/glucose transporter (SGLT) homolog comprising using a polynucleotide.

Group VIII, claim(s) 28-31, 35-38, drawn to a method of inhibiting glucose uptake in the small intestine comprising inhibiting the activity of a Na<sup>+</sup>/glucose transporter (SGLT) homolog.

Group IX, claim(s) 32-34 and 39-41, drawn to a method of promoting glucose uptake in the small intestine comprising promoting the activity of a Na<sup>+</sup>/glucose transporter (SGLT) homolog.

The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups I-IX do not relate to a single general inventive concept because they lack the same or corresponding technical feature.

Claim 1 is directed to a glucose uptake inhibitor in the small intestine comprising a compound or a salt thereof that inhibits the activity of a Na<sup>+</sup>/glucose transporter (SGLT) homolog. Tsujira et al. (J. Med. Chem., 1999, Volume 42, pages 5311-5324, cited in the IDS as CG on page 1) teaches that the antidiabetic agent 4'-dehydroxyphlorizin derivative is absorbed in the small intestine and inhibits the activity of a Na<sup>+</sup>/glucose transporter (SGLT). The prior art meets the limitations disclosed in claim 1. Thus Group I lacks novelty or inventive step and does not make a contribution over the prior art. Since the first claimed invention has no special technical feature, it cannot share a special technical feature with the other claimed invention.

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Under PCR Rule 13.1, the application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### **Species Election**

(1). This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of SGLT homolog base sequence are as follows:

- a) SEQ ID NO:2
- b) SEQ ID NO:4
- c) SEQ ID NO:6
- d) SEQ ID NO:51

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An

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argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner: claim 15, 26.

The following claim(s) are generic: claim 12, 25.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the sequences listed in claim 12 do not share a common feature.

(2). This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of SGLT homolog amino acid sequence are as follows:

- e) SEQ ID NO:1
- f) SEQ ID NO:3
- g) SEQ ID NO:5
- h) SEQ ID NO:50

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Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner: claims 8-11, 19 and 23.

The following claim(s) are generic: claims 1, 16 and 22.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the sequences listed in claim 19 do not share a common feature.

### **Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ian Dang whose telephone number is (571) 272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang  
Art Unit 1647  
Patent Examiner  
February 15, 2007

*Bridget E. Bunner*

**BRIDGET BUNNER  
PATENT EXAMINER**